DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 5, 2015

Fisher & Paykel Healthcare Ltd
Elizabeth Goldstein
Regulatory Affairs Specialist
15 Maurice Paykel Place, East Tamaki
Auckland, 2013 New Zealand

Re: K143646
Trade/Device Name: MR810 System
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: December 18, 2014
Received: January 7, 2015

Dear Ms. Goldstein,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143646

Device Name
MR810 System

Indications for Use *(Describe)*
The Fisher & Paykel MR810 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases, when using a continuous or intermittent ventilator system or a continuous gas flow system.

The MR810 System is intended for both non-invasive and invasive therapies. Addition of heat and humidity to the supply of cold and dry respiratory gases provided through non-invasive or invasive ventilation is beneficial to prevent drying of the patient airways.

The MR810 System is for use for adult and pediatric patients requiring a flow range ≥5 L/min.

The MR810 System is designed for use in hospitals, long term care facilities and homes under the prescription of a qualified medical professional.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5 510(k) Summary

15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

Establishment registration number: 9611451

Contact person/submitter	Elizabeth Goldstein
Date prepared	5 March 2015
Contact details	Address: 15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100 Fax: +64 9 574 0158
Trade name	MR810 System
Common name	Respiratory gas humidifier
Classification name	Respiratory gas humidifier II (21 CFR §868.5450), product code BTT
Predicate device	K131957 MR810 System
Reason for submission	Expanded indications

5.1 Device Description

The Fisher & Paykel MR810 System is intended to heat and humidify breathing gases and therefore meets the definition of a respiratory gas humidifier in accordance with 21 CFR §868.5450 and the FDA guidance document *Heated Humidifier Review Guide*.

The MR810 System consists of the following components:

- MR810 Respiratory Humidifier;
- Accessories:
    - Breathing circuit (e.g. 900MR810 Adult Single Limb Circuit, 900MR810E Adult Dual Limb Circuit); and
    - Humidification chamber (e.g. MR370 reusable humidification chamber).

The MR810 respiratory humidifier is an electrically-powered heat controller which utilizes a microprocessor with embedded software to control the heating elements.

Unconditioned (i.e. cold, dry) gases are delivered to the MR810 System from a gas source (e.g. ventilator) via the dryline component of the breathing circuit. The unconditioned gases are transported to the humidification chamber where they are heated and humidified.

The heated and humidified gases then travel down the inspiratory limb of the breathing circuit. The inspiratory limb of the 900MR810/900MR810E breathing circuits is electrically heated by means of a heaterwire in order to maintain the temperature of the gases. The heater wire is powered by the MR810 respiratory humidifier via a built-in heaterwire adaptor.

When a return flow of expired gases from the patient to the gas source is required, the expired gases are transported via the expiratory limb of the breathing circuit. In other cases, the expired gases from the patient are exhaled into the environment, as per normal, unassisted breathing.

5.2 Intended Use and Indications for Use

5.2.1 Intended Use

The Fisher & Paykel Healthcare MR810 System is intended to provide therapeutic levels of heat and humidity to a patient’s inspired respiratory gases to prevent drying of the patient’s airways.

The intended use of the subject device is identical to the intended use of the predicate device.

5.2.2 Indications for Use

The Fisher & Paykel MR810 System is intended to provide therapeutic levels of heat

and humidity to a patient's inspired respiratory gases, when using a continuous or intermittent ventilator system or a continuous gas flow system.

The MR810 System is intended for both non-invasive and invasive therapies. Addition of heat and humidity to the supply of cold and dry respiratory gases provided through non- invasive or invasive ventilation is beneficial to prevent drying of the patient airways.

The MR810 System is for use for adult and pediatric patients requiring a flow range $\geq$ 5 L/min.

The MR810 System is designed for use in hospitals, long term care facilities and homes under the prescription of a qualified medical professional.

The indications for use of the subject device and the predicate device are *identical* with the exception of the applications for use, where:

- The indications for use statement for the subject device, MR810 System, has been revised to specify the intended patient population and operating flow range.
- The predicate device, MR810 System (K131957), is intended for use for non- invasive applications only.
- The subject device, MR810 System, is intended for use for both non-invasive and invasive applications.

Performance bench testing has been carried out on the MR810 System which verifies that the system is suitable for use for invasive applications.

5.3 Technological Characteristics Comparison

The subject device, MR810 System, is a modification of the predicate device, MR810 System (K131957).

The subject device is *identical* to the predicate device with respect to:

- Principle device design: The subject device, MR810 System, and the predicate device, MR810 System (K131957), have *identical* principle device designs. Both the subject and predicate devices are heated passover humidifiers.
- Patient-contacting components (i.e. material biocompatibility): The subject device, MR810 System, and the predicate device, MR810 System (K131957), have *identical* patient-contacting components (i.e. breathing circuits, e.g. 900MR810 and 900MR810E, and humidification chambers, e.g. MR370).
- Energy source: The subject device, MR810 System, and the predicate device, MR810 System (K131957), use an *identical* energy source. Both the subject and predicate respiratory humidifier devices are powered via mains electricity and the heated breathing circuits are powered by the respiratory humidifier devices.
- Operation: The operation of the subject device, MR810 System, and the predicate device, MR810 System (K131957), is *identical*. Both the subject device and the predicate device have three temperature settings which can be selected by the operator, and two modes of operation which are specific to the type of breathing

circuit used (i.e. heater-wire mode, non heater-wire mode).

- Safety features: The subject device, MR810 System, and the predicate device, MR810 System (K131957), have *identical* safety features. Both the subject device and predicate device have a "see manual" fault indicator, heater wire indicator and shut down mechanisms which render the system inoperable during fault conditions.
- Sterility: The subject device, MR810 System, and the predicate device, MR810 System (K131957), are *identical* in terms of sterility. No components of the subject device or the predicate device are sold sterile, nor are they intended to be sterilized prior to use.
- Reusable accessories: The subject device, MR810 System, and the predicate device, MR810 System (K131957), can be used with *identical* reusable accessories. Both the subject device and predicate device can be used with cleared Fisher & Paykel Healthcare reusable breathing circuits (e.g. 900MR810, 900MR810E) and cleared Fisher & Paykel Healthcare reusable humidification chambers (e.g. MR370).

Minor revisions have been made to sub-components of the MR810 System assembly since submission of K131957. Performance bench testing has been carried out on the modified MR810 System which verifies that the revisions made to the assembly sub-components does not raise any new questions of safety or effectiveness when compared with the predicate device.

5.4 Non-Clinical Performance Data

Bench testing has been carried out on the MR810 System to demonstrate that the differences in indications for use and assembly sub-components does not raise any new questions or safety of effectiveness when compared with the predicate device, MR810 System (K131957).

The following bench testing demonstrates subject and predicate devices are substantially equivalent:

- System-level performance and safety testing in accordance with ISO 8185 *Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems*.
- Basic safety and essential performance testing in accordance with IEC 60601-1 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.
- Basic safety and essential performance in accordance with IEC 60601-1-2 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*.

5.5 Clinical Performance Data

The subject device, MR810 System, is a modification to the legally marketed predicate device, MR810 System (K131957).

Clinical performance data is not required as bench testing was sufficient to demonstrate substantial equivalence to the predicate device.

5.6 Conclusions

The subject device, MR810 System, is a modification to the legally marketed predicate device, MR810 System.

The subject device and the predicate device are *identical* in terms of the intended use, environment for use, principle device design, patient-contacting components and materials, biocompatibility, energy source, operation, safety features, sterility and reusable accessories.

Since submission of K131957, the indications for use of the MR810 System have been expanded to include invasive applications. In addition, minor revisions have been made to MR810 System assembly sub-components. The differences between the subject device and the predicate device do not constitute significant changes in the materials, design, energy source or other features, as demonstrated through bench testing, and therefore the MR810 System is substantially equivalent to the predicate device, MR810 System (K131957).